



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

4678 02 05-5 1106

JUL 31 2002

Ms. Cheryl Verdone  
Vice President of Marketing  
FreeLife International  
333 Quarry Road  
Milford, Connecticut 06460

Dear Ms. Verdone:

This is in response to your letter of July 13, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Carbs Away Plus™** uses the claim "Promote normal, healthy blood sugar levels." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with the first name "John" being more prominent.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, **HFC-200**

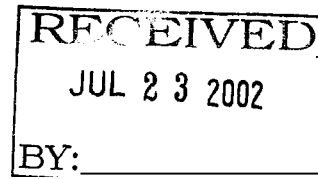
FDA, New England District Office, Office of Compliance, HFR-NE240



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07/13/02

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204



*Re: Notification of Structure/Function Statement(s) for a Dietary Supplement*

Dear Sir or Madam:

Pursuant to §403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §343(r)(6), and 21 CFR §101.93, the undersigned submits the following on behalf of FreeLife, LLC.

**Structure/Function Statements:**

Facilitate natural weight **loss** and maintenance  
Boost your metabolism  
Control your appetite  
Enhance overall energy  
Combat cravings, particularly for refined carbohydrates  
Convert carbohydrates into energy  
Promote normal, healthy blood sugar levels

**Name of Dietary Supplement:** Carbs Away Plus™

I hereby certify that the information contained in this notification is complete and accurate, and that the above listed firm has substantiation that the statements are truthful and not misleading.

Cheryl Verdone  
Vice President of Marketing

8/30/02